

Translation of DE 202 14 019 U1

Ampoule for an injection unit and injection unit for an ampoule

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The invention concerns an ampoule for an injection unit for the needleless injection of a medium into a human or animal tissue, with an ampoule body with a chamber placed inside the ampoule body for admission of the medium with a nozzle for producing a high pressure jet of the medium ejected from the ampoule and with a longitudinally
10 movable piston and a longitudinally movable plug for the restriction of the chamber, whereby the ampoule body show an area separated from the nozzle which is made of a material suitable for a medium and a pressure stable section close to the nozzle. Furthermore, the invention is about an injection unit for an ampoule, wherein the medium to be injected is storageable between a movable plug and a movable piston;
15 with a basic body for the movable admission of a pressure piece that is tightened in the direction of the ampoule by a spring and held by a holding element; with coupling means for the interlocking of the ampoule with the basic body and with a valve lifter placed between the piston on the ampoule and the pressure piece.

20 An injection unit with such an ampoule is for instance known from WO 01/89614. With this ampoule the pressure stable section is formed as a pressure chamber and the area made of a material suitable for a medium is formed as a storage chamber for the medium to be injected. Before the injection the medium is transferred from the storage chamber to the pressure chamber. In doing this the air in the pressure chamber is
25 squeezed out by the medium. With the known ampoule it is possible to establish the area made of a material suitable for the medium to be a lasting storage of the medium and at the same time produce it constructively simple, thin-walled and economical. The section made of pressure stable material shows at one end the nozzle and is production technically essentially more expensive to produce. As the section made of
30 pressure stable material only has to absorb the medium for a short time immediately before the injection, this can be made of a simple, workable and especially economical material, which does not need to provide or allow for a lasting storage for the medium to be injected.

A disadvantage of the known ampoule is however, that the transfer of the medium from the storage chamber to the pressure chamber is very time consuming and attached with losses. Furthermore, the plug close to the nozzle as well as the piston restricting the other end of the chamber are also formed as pistons, so that when injecting two
5 pistons placed close to each other in the pressure chamber have to be shifted. When doing this high, and moreover with different ampoules, strong divergent friction losses, so that the force of the high pressure jets during the injection can only be calculated insufficiently beforehand.

10 It has been considered to provide the nozzle with a hypodermic needle in order to penetrate the plug before the injection. Hereby the piston is the only component of the ampoule that has to be moved during the injection, so that friction forces can be kept especially low. This however requires that the ampoule with the hypodermic needle has to have a further component installed.

15 The problem that is the basis for the present invention is to present an ampoule of the previously mentioned art in such a way, that it is especially economical to produce and that a simultaneous shifting of two pistons during the injection can be avoided. Furthermore, another problem that is the basis for the present invention is to further
20 develop an injection unit of the previously mentioned art in such a way that the ampoule with as little as possible expenditure can be transferred from the pre-filled condition to the ready-to-use condition.

25 The first mentioned problem is solved in accordance with the invention so that a diversion area for the diversion of the plugs via the medium is placed on the end of the pressure stable section turning away from the chamber.

Through this design, the plugs and the pistons as well as the medium confined between these two components are shifted in preparation for the injection until the plug
30 reaches the diversion area and releases the connection of the pressure stable area with the nozzle. After that the medium to be injected is squeezed through the nozzle as a high pressure jet solely via the movement of the piston. The plug is kept in the diversion area during the injection and does not have to be moved. Therefore, because of the invention, the friction losses during the injection are kept especially low. The
35 force of the high pressure jet and with that the penetrating depth of the medium to be

injected in subcutaneous human or animal tissue can when using the ampoule in accordance with the invention be calculated very precisely.

5 Loss through diversion of the plug is kept very low in accordance with an advantageous development of the invention, if the diversion area in the diversion direction is placed immediately in front of the nozzle.

10 In the known ampoule the pressure chamber, the storage chamber and the transfer area are placed behind each other. This causes the ampoule to require large dimensions. The handling of an injection unit provided with the ampoule is therefore very uncomfortable. As the medium to be injected in the ampoule according to the invention compared to the known ampoule does not need to be transferred, the ampoule body can be formed especially short, if the area suitable for the medium and the pressure stable section cross into each other. Hereby the plug can be placed for
15 instance 8 mm from the diversion area, while the chamber for the medium to be injected for instance is 30 mm long. The minimum length of the ampoule according to the invention is therefore 38 mm, while the known ampoule requires a minimum length of 68 mm. The plug and the piston of the ampoule according to the invention therefore have to be shifted 8 mm before the injection in order to provide a connection between
20 the medium and the nozzle.

25 The section suitable for a medium which is crossing into the pressure stable area can be produced especially economical in accordance with another advantageous development of the invention with high stability, if the ampoule body show a tube placed immediately in front of the nozzle made of a material suitable for the medium, and if at least the end of the tube close to the diversion area is surrounded by a pressure stable cover.

30 According to a further development of the invention the ampoule body can be produced especially economical if the tube is made of glass and/or the cover is made of a synthetic material, preferably polycarbonate. In addition to this the ampoule body is especially stable and made of a transparent material.

35 The tube could for instance be sealed by the cover made of synthetic material. The installation of the ampoule body is according to another development of the invention

especially simple if the cover has engagement hooks in order to grasp hold of an edge of the tube.

5 The tube is in accordance with another development of the invention kept reliably in its position opposite the cover, when the tube is supported close to the nozzle through a ring element on a section of the cover. Through the choice of a suitable resilient material it is possible for the ring element to seal the tube, to suppress knocks and to compensate the tolerances in axial direction between the section of the cover and the tube.

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The diversion area is, in accordance with another advantageous development of the invention, designed constructively easy, if it has channels for the diversion of the plugs.

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In accordance with another advantageous development of the invention it is easy to avoid channels close to the nozzle that are expensive to produce, if the diversion area in the movement area of the plug has projections and if the plug is made of a, in radial direction, elastic material. With this the plug is pressed radially together in the diversion area, in order for the medium to flow past between the projection of the wall of the diversion area and the plugs to the nozzle. The projections are preferably formed as ribs turned in the movement direction of the plug and therefore do not lead to an obstruction of the movement of the plug.

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The radial pressing together of the plugs is easily supported if the diversion area is tapering towards the nozzle.

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The ampoule according to the invention is easy to fit to the known injection unit if the cover shows an admission, a thread or a snap connection for the connection with an injection unit. Hereby is the ampoule especially suitable in connection with injection units described in DE 199 55 201 A1 and WO 98/15307, so that for the constructive design of the connection of the ampoule it is distinctly referred to these two publications.

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The second mentioned problem which is the development of an injection unit from the previously mentioned art in a way that the ampoule can be transferred with as little costs as possible from the prefilled condition to the ready-to-use condition, is solved in

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accordance with the invention through adjustment means for the adjustment of the position of the piston in relation to the pressure piece.

5 The ampoule in a prefilled condition can through this design be connected with the basic body. The adjustment means are thereafter adjusted until the valve fitter moves the piston and thereby the plug in the established position for the injection. In addition possible air pockets are squeezed out of the ampoule and the planned injection amount is adjusted. The ampoule is thereby transferred from the prefilled condition to the ready-to-use condition.

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The adjustment means are in accordance with another advantageous development of the invention designed constructively easy if the valve fitter has an external thread corresponding to an internal thread on the pressure piece and if the valve fitter is rotatable in relation to the pressure piece.

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The adjustment of the piston and thereby the plug can in accordance with another advantageous development of the invention happen continuously if the adjustment means show an adjustment screw that is axially movable and torsionally connected with the valve fitter.

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The adjustment screw could for instance form a constructional unit with a locking ring that holds a release on the injection unit in accordance with the invention. The locking ring and the adjustment screw can however be adjusted independently of each other in accordance with another advantageous development of the invention, if the adjustment screw is placed on the end of the basic body that is turning away from the ampoule and if the valve fitter breaks through the pressure piece.

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30 The installation of the ampoule on the basic body happens comfortably in accordance with another advantageous development of the invention, if the coupling means on the basic body show engagement hooks and if an adjustment ring that connects interlockingly with the engagement hooks has a thread corresponding to the thread on the ampoule for the adjustment of the position of the piston in relation to the pressure piece.

The invention allows for several embodiments. For further illustration of the basic principles several of them are described in the drawings and are described afterwards. They show:

- 5 Fig. 1 an injection unit with an ampoule in accordance with the invention before the installation on a basic body in a longitudinal section,
- Fig. 2 a considerable enlarged presentation of detail II from figure 1,
- 10 Fig. 3 a further embodiment of the ampoule in accordance with the invention,
- Fig. 4 a further embodiment of the ampoule in accordance with the invention,
- Fig. 5 a further embodiment of the injection unit in accordance with the invention,
- 15 Fig. 6 an enlarged presentation of detail VI from figure 5,
- Fig. 7 a further embodiment of the injection unit in accordance with the invention,
- 20 Fig. 8 an enlarged presentation of detail VIII from figure 7.

Figure 1 shows an ampoule 2 in an injection unit that is connected with a basic body 1. Such basic bodies 1 and injection units are described in detail in DE 199 55 201 A1 and WO 98/15307, so that for various embodiments of the basic body 1 and the injection unit it is specifically referred to these publications. The basic body 1 has a pressure piece 5 that is tightened through a spring element 3 against a holding element 4. The pressure piece 5 is led into the basic body 1 longitudinally movable. The holding element 4 is via a release 6 in a first position in the pressure piece 5 kept against the force of the spring element 3 in the drawn in position, and in a second position in which the movement of the pressure piece 5 is released, movable. A valve fitter is placed on the pressure piece 5 and has a larger diameter on its free end than in the middle area. The ampoule 2 has an ampoule body 8 with a chamber 9 for the admission of a medium to be injected. The chamber is cylindrical and is restricted with a longitudinally movable piston 10 and a plug 11. In addition the ampoule body 8 has a tube 12 made of glass and a cover 13 surrounding the tube 12 preferably made of a translucent

synthetic material, such as for instance polycarbonate. The cover 13 has engagement hooks 14 for grasping hold of the tube 12 and an admission 15 for the connection with a corresponding admission 16 on the basic body 1. A thread is for example described in the figures as an admission 15,16. The admissions 15,16 thereby form coupling means for the interlocking connection of the ampoule 2 with the basic body 1. The ampoule 2 is screwed in the required position in the basic body 1 by rotation.

The tube 12 is made of a material suitable for the medium and forms an area for the storage of the medium. The cover 13 is made of a pressure stable material and supports during injection influencing forces on the tube 12. Alternatively the tube 12 can be made so thick-walled that it can support the forces occurring during injection. The cover 13 would then only serve as an economical holding of the tube 12. The area for the storage of the medium and the pressure stable section of the ampoule 1 are thereby crossing into each other. The plug 11 is placed immediately in front of a diversion area 18 adjacent to a nozzle 17. The filled ampoule 2 can in this condition be stored permanently.

As preparation for the injection, the piston 10 is pushed into the chamber 9 via the valve fitter 7 either by hand or by screwing the ampoule 2 into the basic body 1, until the plug 11 is pressed into the diversion area 18 via the medium and a connection between the chamber 9 and the nozzle 17 is made. After installation of the ampoule 2 on the basic body 1 the nozzle 17 is then placed on the skin of the human being or the animal for the injection and the release 6 is pushed down. Following that the pressure piece 5 is shifting the piston 10 via the force of the spring element 3. The piston 10 decreases the volume of the chamber 9 in order for the medium via the skin to enter the subcutaneous tissue via the nozzle 17 as a high pressure jet.

The medium to be injected can be any drugs, anaesthetics, hormones or such used in medicine or dental medicine that are suitable to be injected into the tissue as high pressure jets.

Figure 2 shows considerably enlarged with the details II from figure 1 the end of the ampoule 2 with the nozzle 17 and the diversion area 18. It is recognisable that the diversion area 18 of the ampoule 2 shows the approximately same diameter as the tube 12. The plug 11 can thereby be pushed into the diversion area 18 with less force.

Furthermore, there are groove-like channels 19 placed in the wall of the diversion area 18. The channels 19 have at least the same height as the plug 11, so that via the plug 11 that is pressed into the diversion area 18, through the channels 19 it is possible to get a connection between the chamber 9 containing the medium and the nozzle 17.

5 The injection is therefore not obstructed by the plug 11. Figure 2 furthermore shows that a ring element 21 made of a resilient material is placed between the tube 12 and a section 20 of the cover 13.

Figure 3 shows a further embodiment of the ampoule, that only differs from the one in figure 1 and 2 in that a diversion area 22 for the plug 11 shows nose-like projections 23 penetrating the movement area of the plug 11. The plug 11 is formed in a radial resilient way and is pressed together by the position of the projections 23 in the diversion area 22. The medium from the chamber 9 can thereby divert the plugs 11 between the projections 23. This ampoule has an admission 24 formed as a rotating ring for connection with a not described basic body with engagement hooks.

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Figure 4 shows a further embodiment of the ampoule 2, where an area for the storage of the medium with a tube 25 made of glass is spatially separated from a pressure stable section. A diversion area 26 for the plug 27 is placed on the end of the pressure stable section close to a nozzle 28, and formed taperingly towards the nozzle 28. Channels 29 are furthermore placed in the diversion area 26. The plug 27 has a form corresponding to a piston 30 and is resiliently formed. In the shown storageable condition of the ampoule 2 the medium to be injected is kept in a chamber 31 formed between the plug 27 and the piston 30 and the tube 25. As preparation for the injection the piston 30 is pressed into the chamber 31. The medium thereby presses the plug 27 via the pressure stable section into the diversion area 26. When the plug 27 is in the diversion area 26 the medium to be injected can advance via the channels 29 past the plug 27 to the nozzle 28. The ampoule 2 can after that for instance be connected with the basic body described in figure 1, and eject the medium as a high pressure jet through the nozzle 28.

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Figure 5 show a further embodiment of the injection unit whereby the ampoule 2 has a snap connection 32 with a basic body 33. As in the embodiments of figure 3 and 4 the ampoule 2 in filled condition can therefore easily be attached to the basic body 33. The ampoule 2 is thereby via the snap connection 32 interlocked with the basic body 33, as

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shown in figure 5. A valve fitter 34 connected to the piston 10 on the ampoule 2 is guided through a pressure piece 35 on the basic body 33 and axially movable and torsionally connected to an adjustment screw 36. In figure 6 the illustration of the connection of the valve fitter 34 with the pressure piece 35 is shown enlarged. By rotating the adjustment screw 36 the valve fitter 34 can rotate in the pressure piece 35 and thereby be screwed into or out of this piece. The piston 10 is thereby moved in or out of the ampoule 2 and the plug 11 is shifted via the medium in the chamber 9 until it is in the position where the ampoule 2 is prepared for the injection. Moreover the function of the injection unit shown in figures 5 and 6 is the same as the injection unit shown in figure 1. With regard to the ampoule 2 it can be one of the embodiments described in figures 1 to 3. However other embodiments of ampoules 2 for the injection unit can be used, where the ampoules can be transferred by shifting the piston 10 from a condition where they are stored to a ready-to-use condition.

Figure 7 shows an injection unit that mostly differs from the one shown in figure 1 by the fact that an adjustment ring 40 with radially engagement projections 41 that stick out is untwisted on the thread 39 of the ampoule 2. The connection of the ampoule 2 with a basic body 44 on the injection unit is shown enlarged in figure 8 for clarification. The adjustment ring 40 has a thread 42 for connection with the ampoule 2. Engagement hooks 43 on a basic body 44 overlap the engagement projections 41 on the adjustment ring 40. In order to change the position of the piston 10 on the ampoule 2 in relation to a pressure piece 45 in the basic body 44, it is possible to rotate the ampoule 2 in relation to the adjustment ring 40, and thereby to screw the ampoule 2 in or out of the basic body 44.

Claims

1. Ampoule for an injection unit for the needleless injection of a medium into a human or animal tissue, with an ampoule body with a chamber placed inside the ampoule body for admission of the medium with a nozzle for producing a high pressure jet of the medium ejected from the ampoule and with a longitudinally movable piston and a longitudinally movable plug for the restriction of the chamber whereby the ampoule body show an area separated from the nozzle which is made of a material suitable for a medium and a pressure stable section close to the nozzle, characterised in that a diversion

area (18, 22, 26) for the diversion of the plug (11, 27) via the medium is placed on the end of the pressure stable section that turns away from the chamber (9, 31).

- 5 2. Ampoule according to claim 1, characterised in that the diversion area (18, 22, 26) viewed from the flow direction is placed directly in front of the nozzle (17, 28).
- 10 3. Ampoule according to claim 1 or 2, characterised in that the area suitable for the medium and the pressure stable section cross into each other.
- 15 4. Ampoule according to at least one of the preceeding claims, characterised in that the ampoule body (8) show a tube (12) directly in front of the nozzle (17) made of a material suitable for a medium and that the diversion region (18, 22) close to the end of the tube (12) is surrounded by a pressure stable cover (13).
- 20 5. Ampoule according to at least one of the preceeding claims, characterised in that the tube (12) is made of glass and/or that the cover (13) is made of synthetics, preferably polycarbonate.
- 25 6. Ampoule according to at least one of the preceeding claims, characterised in that the cover (13) has engagement hooks (14) for grasping hold of an edge of the tube (12).
- 30 7. Ampoule according to at least one of the preceeding claims, characterised in that the tube (12) close to the nozzle (17), supports itself through a ring element (21) on a section (20) of the cover (13).
8. Ampoule according to at least one of the preceeding claims, characterised in that the diversion area (18, 26) has channels (19, 29) for the diversion of the plug (11, 27).
9. Ampoule according to at least one of the preceeding claims, characterised in that the diversion area (22) in the movement area of the plug (11) show

penetrating projections (23) and that the plug (11) is made of a, in radial direction, resilient material.

- 5 10. Ampoule according to at least one of the preceeding claims, characterised in that the diversion area (26) running towards the nozzle (28) is constructed in a tapering way.
- 10 11. Ampoule according to at least one of the preceeding claims, characterised in that the cover (13) show an admission (15, 24), a thread (39) or a snap connection (32) for the connection with an injection unit.
- 15 12. Injection unit for an ampoule, in which an injection medium is storageable between a movable plug and a movable piston, with a basic body for the movable admission of a pressure piece tightened with a spring in the direction of the ampoule and held by a holding element, with coupling means for the interlocking of the ampoule with the basic body and with a valve lifter placed between the piston on the ampoule and the pressure piece, characterised in an adjustment means for the adjustment of the position of the piston (10) to the pressure piece (5, 35, 45).
- 20 13. Injection unit according to claim 12, characterised in that the valve lifter (34) has an external thread (38) corresponding to an internal thread (37) of the pressure piece (35) and that the valve lifter (34) is rotatable to the pressure piece (35).
- 25 14. Injection unit according to claim 12 or 13, characterised in that the adjustment means show a adjustment screw (36) axially removable and rotatably connected with the valve lifter (34).
- 30 15. Injection unit according to one of the claims 12 to 14, characterised in that the adjustment screw (36) is placed on the end of the basic body (33) turning away from the ampoule (2) and that the valve lifter penetrates the pressure piece (35).
- 35 16. Injection unit according to one of the claims 12 to 15, characterised in that the coupling means show engagement hooks (43) placed on the basic body (44)

and that an adjusting ring (40) which is interlocked with the engagement hooks (43) has a thread (42) corresponding to a thread on the ampoule (2) for the adjustment of the position of the piston (10) to the pressure piece (45).

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